

K970992

JUN 17 1997

SUMMARY OF SAFETY AND EFFECTIVENESS
INFORMATION

1. Submitter's Information -

Name and Address:

Premier Dental Products Co.
3600 Horizon Drive
Box 61574
King of Prussia, PA 19406-0974

Telephone Number (215) 676-9090

Contact Person Mr. William J. Frezel

Date Prepared March 15, 1997

2. Names for the Device -

Classification Name: Cryosurgical Unit and Accessories (79GEH)

Common Name: Cryosurgical Unit

Proprietary Name: Premier Nitrospray Plus and Premier Nitrospray Lite Plus

3. Legally Marketed Devices -

The Premier Nitrospray Plus cryosurgical device is substantively equivalent to those offer by:

Wallach Surgical Devices Inc.

Galderma Laboratories/ Brymill Corporation

Center Laboratories

Table 1 compares the Premier Nitrospray device to the predicate devices.

4. Description of Product and Function -

The Premier Nitrospray Plus consists of a stainless steel vacuum bottle reservoir in various volumes, a screw-on cap with control valve and handle assembly and a pressure relief valve mounted thereon. After filling the reservoir with liquid nitrogen the cap/valve assembly is screwed onto the reservoir to a snug fit. Complete directions for use can be found in Appendix 3.1.

To use the device the professional first attaches an accessory tip to the spray tube luer fitting and points the tip towards the treatment area. Pulling on the handle activates the device by opening the control valve which allows the cold nitrogen gas to be expelled through the tip and onto the target tissue. The length of time and area of exposure is controlled by the professional through the use of the control valve handle and the direction in which the tip is pointed.

The legally marketed predicate devices listed in section 3 utilize the substantively equivalent method for accomplishing the same basic treatment procedure. The directions for use of these devices can be found in Appendices 3.3 and 3.4.

The cap/ valve assembly has a safety relief valve mounted thereon to vent the gaseous nitrogen when the internal pressure exceeds the valves preset limit of 7.5 p.s.i.

Another similar cryosurgical device also utilizing liquid nitrogen is currently marketed by Premier. This device based on an open system design is activated by closing a finger port to the atmosphere thereby allowing pressure to build in the reservoir resulting in the expulsion of nitrogen gas through a spray tip. This device was originally designed and manufactured by Tower Manufacturing Co. San Antonio ,TX. In 1995 Premier purchased from Tower the rights to manufacture and distribute the device. The Tower open system design received 510(k) marketing clearance through K #872796.

5. Intended Use -

The intended use of the Premier Nitrospray Plus cryosurgical device is to provide a means for transporting liquid nitrogen to the patient and to dispense the liquid nitrogen as a cold gas in a controlled manner. The gaseous nitrogen when dispensed is at a temperature of -196°C.

An article written by E. G. Káflík, MD in the December 1994 issue of Journal of the American Academy of Dermatology summarizes the intended use (page 928) and the complications (page 931) of this well established treatment modality. The article also includes descriptions of the conditions which can be treated (pages 928 - 938). Techniques of treatment are described as well as cure rates for various conditions. A copy of the article is found in Appendix 3.5.

This cryosurgical device is to be used only by licensed clinicians and is so labeled.

6. **Technical Characteristics -**

A comparison summary of the Premier Nitrospray Plus cryosurgical device to the predicate devices is given in Table 1.

An assembly drawing of the Premier Nitrospray is contained in Appendix 3.2.

TABLE 1

COMPARISON OF PREMIER NITROSpray PLUS TO PREDICATE DEVICES

MANUFACTURED BY	Premier Dental Products Co	Premier Dental Products Co	Wallach Surgical Devices	Brymill Corp.	Not Known
MANUFACTURED FOR				Galderma Labs.	Center Laboratories
PROPRIETARY NAME	Nitrospray Plus	Nitrospray Plus Lite	UltraFreeze	CRY-AC and CRY-AC-3	CryoJet Model 8300
510(k) NUMBER	To Be Assigned	To Be Assigned	Not Known	Not Known	Not Known
METHOD OF OPERATION	Finger Activated Valve	Finger Activated Valve	Finger Activated Valve	Finger Activated Valve	Finger Activated Valve
COOLING MEDIA	Liquid Nitrogen	Liquid Nitrogen	Liquid Nitrogen	Liquid Nitrogen	Liquid Nitrogen
RESERVIOR VOLUME	16 oz / 0.47 l	10 oz. / 0.30 l	0.55 l and 0.30 l	0.50 l and 0.30 l	0.5 l
TIP LOCKING MECHANISM	Luer Lock Fitting	Luer Lock Fitting	Luer Lock Fitting	Threaded Tip	Special Design
RESERVIOR MATERIAL	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel	Plastic Material
CAP MATERIAL	Delrin	Delrin	Plastic Material	Stainless Steel	Plastic Material
PRESSURE RELIEF SETTING	7.5 psi	7.5 psi	Operator Adjustable	7.5 psi	7.5 psi
ACCESSORIES	Spray Tips	Spray Tips	Spray Tips	Spray Tips	Spray Tips



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. William J. Frezel
Executive Vice President
Premier Dental Products Company
10090 Sandmeyer Lane
Philadelphia, Pennsylvania 19116-3502

JUN 17 1997

Re: K970992
Trade Name: Premier Nitrospray Plus and Premier Nitrospray Lite Plus
Regulatory Class: II
Product Code: GEH
Dated: March 15, 1997
Received: March 19, 1997

Dear Mr. Frezel:

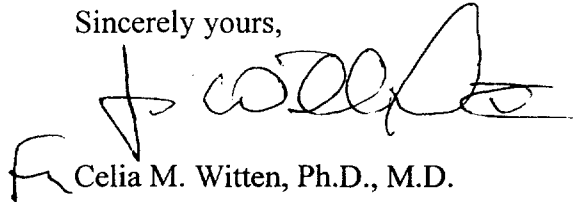
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over a horizontal line.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K970992

Device Name: Premier Nitrospray Plus and Premier Nitrospray Lite Plus

Indications For Use:

To provide a means for transporting liquid nitrogen to the patient and to dispense the liquid nitrogen as a cold gas in a controlled manner during general or dermal cryosurgical procedures. The gaseous nitrogen, when dispensed, is at a temperature of -196°C.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K970992

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)